

## REMARKS

Claims 1, 16-19, 31, 37, 49 and 57 are amended to recite that the pharmaceutical composition is a tablet, as taught throughout the specification. Claims 1-37 and 40-60 are presented for reconsideration.

The sole issue raised in the Office Action is the rejection of claim 22 under the second paragraph of §112. Applicant believes that the rejection is meant to apply to claim 32.

Claim 32 recites that the “mixing and formation of a granulate are performed in a single integrated machinery that is adapted for such a combined process.” The Office Action alleges that the claim does not particularly point out the machinery used in the process, and suggests revising the claim to recite the machinery listed at page 11 of the specification, in lines 28-37. Applicant respectfully traverses this rejection.

Applicant believes that claim 32 as written fully satisfies the requirements of §112, second paragraph. The claim is directed to an embodiment of the invention where the “mixing and formation of a granulate are performed in a single integrated machinery.” Those skilled in the art readily will understand the metes and bounds of the claim as written. The specification provides an example of suitable machinery, but the invention is not limited to the use of the exemplified machinery. Amending the claim to recite specific machinery would unnecessarily restrict the scope of the claim.

Applicant notes that the embodiment of claim 32 is described at page 12, lines 1-7, not at page 11, lines 28-37, cited in the Office Action. (Page 11 describes exemplary tablet compressing equipment.) As explained at page 12, suitable integrated machinery for mixing and formation of a granulate are known in the art as “one-pot equipment” and are exemplified by the FT series, provided by Forberg A/S Norway. The plain language of claim 32 as written, read in light of these teachings, particularly points out and distinctly claims the subject matter of claim 32. Applicant therefore respectfully urges the Examiner to reconsider and withdraw the §112, second paragraph rejection.

Applicant submits herewith an Information Disclosure Statement to submit references cited in co-pending U.S. patent application 10/425,993. The submitted references are the U.S. counterparts of WO 01/78694 and WO 01/78695 already considered by the Examiner.

Applicant believes that the application is now in condition for allowance, and an early notice to that effect is earnestly solicited. Should there be any questions regarding this submission, or should any issue remain, the Examiner is invited to contact the undersigned attorney of record at the telephone number set forth below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date July 14, 2005

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 295-4094  
Facsimile: (202) 672-5399

By Courtenay C. Brinckerhoff

Courtenay C. Brinckerhoff  
Attorney for Applicant  
Registration No. 37,288